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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,331	12/12/2003	Ronald Yamamoto	MNOAP004	3792

23689 7590 10/11/2006

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EXAMINER

BLEIBEL, NASSEIM K

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/735,331	<b>Applicant(s)</b> YAMAMOTO ET AL.	
	<b>Examiner</b> Nasseim Bleibel	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 12/12/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>09/02/2004</u> . | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed WO 01/12071 and Mattrey which fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-11, 13-15, 17, 18 are rejected under 35 U.S.C. 102(b) as being Anticipated by Liberman (<http://www.ajronline.org/cgi/content/full/177/4/887>). Liberman discloses all the limitations of the claims including the following: injecting a radiological contrast agent into the human breast, identifying a sentinel lymph node via an imaging modality, (Liberman, materials and methods paragraph 3) introducing a percutaneous excision devise and excising the identified sentinel lymph node using an imaging modality (Liberman, materials and methods paragraph 5). Medical imaging selected from ultrasound, computerized tomography, or magnetic resonance imaging was used,

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percutaneous biopsy, sonographis or stereotactic guidance as Liberman shows in the materials and methods section paragraph 2. Liberman shows the use of radiological agent as well as blue dye, which can be used to identify the sentinel lymph node after the excision (materials and methods paragraph 3). The radioisotope can be detected using a gamma counter as shown in materials and methods paragraph 4 of Liberman.

4. Liberman discloses injecting a radiological contrast agent and a second agent, blue dye, into the human breast and uses the radiological contrast agent to get an image of a lymph node; (materials and methods paragraph 3) then uses the image to locate and excise the lymph node using a percutaneous excision device (materials and methods paragraph 5). The use of the blue dye is then used via visual inspection to confirm identification of the sentinel lymph node (Materials and methods paragraph 5).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2,12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liberman as applied to claim 1 above and further in view of Siczek 5,569,266 or Carroll 6,205,352. The reference applied to claim 1 discloses all the limitations except for the use of ultrasound, computerized tomography scanning, or magnetic resonance imaging to aid in at least one of the introducing and excising of the identified sentinel

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lymph node and excision device. Siczek teaches the use of magnetic resonance imaging to aid in excising lesions in the breast that are suspected of being cancerous. Therefore, it would be obvious, in view of Siczek or Carroll, to one of ordinary skill in the art at the time of the invention was made to use Medical resonance imaging to aid in the excising of the sentinel lymph node in conjunction with what was disclosed in the reference of claim 1.

### ***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure and are cited on form 892 enclosed herewith.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bleibel Nasseim whose telephone number is (571)272-2796. The examiner can normally be reached on M-F 8AM to 4:30PM.

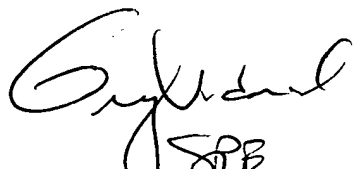
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Casler Brian can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nasseim Bleibel  
Examiner  
Art Unit 3737

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